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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,423	09/10/2003	Tammy Burd Mehta	100/03021	4629

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CALIPER LIFE SCIENCES, INC.
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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,423

Applicant(s)

MEHTA, TAMMY BURD

Examiner

Christopher M. Babic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-10 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/10/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et al. (U.S. 6,306,590).

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

These claims are drawn to a method performing PCR and separating one or more PCR products, the method comprising: (i) mixing one or more PCR

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reaction components with a sieving medium to provide a PCR sieving medium, wherein the sieving medium comprises a polymer solution, which polymer solution comprises less than about 0.5% polymer; and (ii) thermocycling the PCR sieving medium to produce one or more PCR products; and, (iii) separating the one or more PCR products by flowing the one or more PCR products through the sieving medium.

Regarding Claim 1, Mehta et al teach a method of performing PCR and separating one or more PCR products by mixing PCR components with a sieving matrix, thermocycling to produce one or more PCR products, and performing electrophoresis to separate the PCR products (*Column 17, Lines 13-52*; *Columns 27-28, Example 2*). Furthermore, Mehta et al. teaches a polymer solution of 0.5% polymer (*Column 28, Lines 4-20*). These methods clearly lie within the meets and bounds of the claim language, "less than about 0.5% polymer", and therefore anticipate the methods of Claim 1.

Regarding Claims 4-6, Mehta et al. teach polymer solutions of linear polyacrylamide and methyl cellulose (*Column 28, Lines 4-20*).

Regarding Claim 7, Mehta et al teach a PCR master mix with all of the components of Claim 7 (*Column 28, Lines 20-32*).

Regarding Claim 8-9, Mehta et al. teach a PCR reaction in the presence of DNA separating gels in a microfluidic system, and that the resulting PCR products are separable in the gel in a microfluidic system (*Columns 27-28, Lines 67-67 and 1-3*).

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Regarding Claim 10, Mehta et al. teach separation by electrophoresis
(Column 28, Lines 42-67).

Prior Art Search

No prior art teaching has been found teaching or suggesting the methods and limitations of Claims 2 and 3. The closest prior art found was Mehta et al. who did not teach or suggest the use of sieving medium comprising a polymer solution of any less than 0.5% polymer. Waters et al. is cited as a reference of interest (*Microchip Device for Cell Lysis, Multiplex PCR Amplification, and Electrophoretic Sizing. Anal Chem. 1998 Jan 1; 70(1): pages 158-162, See Experimental Section*). Waters teaches a microfluidic device in which a multiplex PCR amplification and electrophoretic analysis are carried out in two separate sequential process steps. Waters et al method teaches injecting a PCR product into a sieving medium after an amplification step. Waters et al does not teach carrying out a PCR reaction in the presence of a sieving medium.

Claim Status

1. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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No claims allowed.

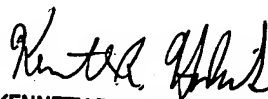
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMB

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6/9/05


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

6/9/05